

In the claims:

The following claims are or have been pending in the present application:

1. (Presently amended) An A-hand-held, portable, aerosol drug delivery system, comprising:
a disposable container ²⁸ adapted to contain ~~containing~~ a drug formulation;
an aerosol generator for aerosolizing the drug formulation in response to manual actuation; and
a prevention device which prevents aerosolization of ~~access to~~ the drug formulation when in an inactive state and which permits aerosolization of ~~access to~~ the drug formulation when in an activated state.
2. (Original) A system as in claim 1, wherein the prevention device comprises an electronic lockout device having a lockout element that is positioned in a dose preventing position when in the inactive state, and is movable to a dosing permitting position when electric current is supplied to place the lockout device in the activated state.
3. (Original) A system as in claim 2, wherein the lockout device further comprises circuitry for supplying electrical current to move the lockout element to the dose permitting position when the lockout device is in the activated state.
4. (Original) A system as in claim 2, wherein the lockout device further comprises a controller having an associated memory for storing a dosing condition, and wherein the controller is configured to send a signal to place the lockout device in the activated state only after the dosing condition has been satisfied.
5. (Original) A system as in claim 2, wherein the container comprises a canister, and wherein the aerosol generator comprises a metering valve and an actuator operably coupled to the canister.
6. (Original) A system as in claim 5, further comprising a housing, wherein the canister is reciprocally held within at least a portion of the housing between a home position and a dosing position where the actuator is engaged to open the metering valve and to permit the escape of a metered amount of the drug formulation from the canister.

7. (Original) A system as in claim 6, wherein the lockout element is positioned to prevent engagement of the actuator when in the dose preventing position to thereby prevent opening of the metering valve.

8. (Original) A system as in claim 7, wherein the lockout element has a distal end that is engageable with the canister to prevent substantial displacement of the canister into the housing when the lockout element is in the dose preventing position.

9. (Original) A system as in claim 8, wherein upon placement of the preventing device into the activated state, the distal end of the lockout element is retracted to permit displacement of the canister into the housing and to permit engagement of the actuator to open the metering valve.

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10. (Withdrawn) A system as in claim 7, wherein the canister is movable within the housing when the preventing device is in the inactive state, and further comprising a stop that is reciprocally disposed within the housing below the actuator, and wherein the lockout element has a distal end that is engageable with the stop when in the activated state to prevent movement of the stop within the housing such that displacement of the canister engages the actuator with the stop to permit dispensing of the metered drug formulation when the preventing device is in the activated state.

11. (Original) A system as in claim 1, further comprising a high pressure gas source to assist in aerosolizing the drug formulation when the preventing device is in the activated state.

12. (Original) A system as in claim 1, further comprising a dose counter disposed to count the number of doses of the drug formulation dispensed from the container.

13. (Original) A system as in claim 12, wherein the container is reciprocatably disposed within a housing, and wherein the dose counter comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing.

14. (Original) A system as in claim 13, wherein the dose counter further comprises a display for indicating if the container contains an amount of drug formulation.

15. (Presently amended) A system as in claim 5, further comprising a nozzle operably operable-coupled to the canister, and wherein the housing further includes a mouthpiece disposed to receive the drug formulation from the nozzle.

16. (Original) A system as in claim 15, wherein the mouthpiece has a first end and a second end, and wherein the nozzle is positionable within an opening adjacent the first end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a patient upon inhalation through the second end of the mouthpiece.

17. (Presently amended) A method of aerosolizing for administering a drug formulation, the method comprising:

providing a container having an amount of a drug formulation that is aerosolized in response to manual actuation;

preventing the aerosolization transfer of the drug formulation from the container with an electronic lockout device by maintaining when the lockout device is in an inactive state; and

supplying electrical current to the lockout device to place the lockout device in an active state, thereby permitting the aerosolization transfer of the drug formulation from the container.

18. (Original) A method as in claim 17, wherein the electronic lockout device comprises a lockout element that is positioned in a dose preventing position when in the inactive state, and further comprising moving the lockout element to a dosing permitting position when electric current is supplied to place the lockout device in the activated state.

19. (Original) A method as in claim 18, wherein the container comprises a canister having a metering valve and an actuator, wherein the canister is reciprocatably held within a housing between a home position and a dosing position, and further comprising depressing the canister into the housing to the dosing position to engage the actuator and to release a metered amount of the drug formulation when the lockout device is in the active state.

20. (Original) A method as in claim 19, further comprising preventing engagement of the actuator when the lockout element is in the dose preventing position.

21. (Original) A method as in claim 20, further comprising engaging the canister with the lockout element to prevent movement of the canister to the dispensing position when the lockout element is in the dose preventing position.

22. (Original) A method as in claim 21, further comprising disengaging the lockout element from the canister to permit movement of the canister to the dispensing position upon supply of the electrical current.

23. (Withdrawn) A method as in claim 20, further comprising engaging the lockout element with a stop that is positioned below the actuator upon supply of the electrical current, and further comprising depressing the canister into the housing to engage the actuator with the stop.

al 24. (Presently amended) A method as in claim 18, further comprising stopping the supply of the electric current to the lockout device after the drug formulation has been aerosolized ~~transferred from the container~~.

25. (Presently amended) A method as in claim 24, further comprising supplying electric current to the lockout device to permit another dosing only after a certain dosing condition has ~~conditions~~ have been satisfied.

26. (Presently amended) A method as in claim 25, further comprising counting the number doses aerosolized ~~transferred~~ from the container.

27. (Presently amended) A method as in claim 26, further comprising displaying whether the container contains an amount of drug formulation based on the number of aerosolizations ~~counts~~.

28. (Presently amended) An ~~hand-held, portable~~, aerosol drug delivery system, comprising:

a housing having a mouthpiece;
a canister that is movable within the housing when manually depressed into the housing, the canister having a metering valve that is operable to release a metered amount of a drug formulation from the canister; and

a control system comprising a locking mechanism that may be in an activate or an inactive state, wherein the control system controls the re-control-opening of the valve such that the valve is only opened when a force is manually applied to depress the canister into the housing and when a dosing condition has been satisfied at which time the locking mechanism in the active state.

29. (Presently amended) A system as in claim 28, wherein the control system comprises a controller ~~and a locking mechanism~~, wherein the controller is configured to send a signal to the locking mechanism to activate the locking mechanism to permit opening of the valve once the dosing condition has been satisfied.

30. (Original) A system as in claim 29, wherein the dosing condition is the passage of a certain amount of time between dosings, and further comprising an electronic clock coupled to the controller to measure the passage of time between dosings.

31. (Original) A system as in claim 28, wherein the locking mechanism is normally in a dose preventing position and is movable to a dosing position when electrical current is supplied to the locking mechanism to permit opening of the valve when the canister is depressed.

32. (Presently amended) A system as in claim ~~28~~ 31~~28~~, wherein the locking mechanism includes a locking element that engages the canister to prevent depression of the canister into the housing when in the dose preventing position.

33. (Withdrawn and Presently amended) A system as in claim ~~28~~ 31~~28~~, wherein the canister includes an actuator, and wherein the locking mechanism includes a locking element that engages a stop that in turn engages the actuator when in the dose permitting position and when the canister is depressed into the housing.

34. (Presently amended) A method for administering a nicotine formulation for smoking cessation therapy, the method comprising:
providing an amount of a nicotine formulation;
preventing the aerosolization of the nicotine formulation with a lockout device when the lockout device is in an inactive state;

supplying electric current to the lockout device to place the lockout device in an active state; and aerosolizing the nicotine formulation by manual actuation.

al 35. (Original) A method as in claim 34, further comprising controlling when electric current may be supplied to the lockout device based on a specified dosing schedule.

36. (Presently amended) A system as in claim 1, wherein the container contains drug formulation which comprises nicotine.
